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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

MEHTA, ASHWIN D

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 01/30/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/057,775

Applicant(s)

TIETZ, RODNEY L.

Examiner

Ashwin Mehta

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 25 January 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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DETAILED ACTION

Specification

1. The specification is objected to for the presence of blank lines on pages 5, 10, 22, and 29.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The recitation "I390186" in claims 1, 2, 5, 14, 15, 17, 20-22, and 31 render the claims and those dependent thereon indefinite. Since the name "I390186" is not known in the art, the use of said name does not carry art-recognized limitations as to the specific or essential characteristics that are associated with that denomination. The name "I390186" does not clearly identify the claimed seeds, plants, and plant parts, and does not set forth the metes and bounds of the claimed invention. The name appears to have been arbitrarily assigned and can be changed. The specific characteristics associated therewith can also be modified. Claims 1, 2, 5, 14, 15, 17, 20-22, and 31 are also indefinite for failing to identify the ATCC accession number. Amending claims 1, 2, 5, 14, 15, 17, 20-22, and 31 to recite the ATCC deposit number in which seed of corn inbred line I390186 has been deposited would overcome the rejection.

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In claim 2: the recitation "population of seed of the corn variety I390186" renders the claim indefinite, because it is not clear if the population only consists of I390186 seed or if it also comprises other seed. The specification at page 6 indicates that a population of inbred seed can further be defined as being essentially free from hybrid seed (lines 11-14). However, the specification does not provide a definition for "population." Claim 2 indicates that the population is of only I390186 seed. However, the recitation on page 6 indicates the populations may comprise other seed. It is not clear if the population of claim 2 consists only of I390186 seed, or if it also comprises other types of seed.

In claims 3 and 4: the claims are indefinite because they broaden the scope of the claim from which it depends. Claim 2 is drawn towards a population of seed of corn variety I390186. Claim 2 does not make any mention of any other seed variety being part of the population. However, claim 3 encompasses essentially homogeneous populations of I390186 seed, which can comprise other types of corn seed. Similarly, the population of claim 4 can contain hybrid corn. Given the confusion over the definition of the word "population" as discussed above, if the population of claim 2 only consists of seed I390186, then claims 3 and 4 broaden the scope of claim 2.

In claim 14: the recitation "An essentially homogeneous population of corn plants produced by growing the seed of the corn variety I390186" in lines 1-2 renders the claim indefinite. The I390186 seed can only produce I390186 plants. The population can therefore only consist of I390186 plants. It is then not clear why the population is referred to as "essentially homogeneous," since such populations can be comprised of more than one type of plant.

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The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 2-4, 14, and 24-31 rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are broadly drawn towards an a population, or an essentially homogeneous population, of seed of corn variety I390186, or a population of I390186 seed essentially free of hybrid seed; an essentially homogeneous population of corn plants produced by growing seed of I390186; any hybrid corn seed produced by crossing corn plant I390186 with any second, distinct inbred corn plant; any hybrid corn plant produced by growing said hybrid seed; inbred corn plant I390186 further comprising any single locus conversion; a method of producing inbred corn plant derived from corn variety I390186 comprising crossing I390186 plants with any second corn plant, and crossing the progeny with itself or any other plant to produce further progeny.

The specification describes numerous morphological and physiological characteristics of corn plant I390186 (page 24, line 1 to page 28). The specification also indicates that essentially homogeneous populations of inbred seed are those in which the inbred seed forms about 90% to about 100% of the total seed (page 5, lines 18-22). The specification also indicates that populations of inbred seed can be further defined as being essentially free of hybrid seed, which

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may indicate that populations of inbred seed can also comprise other seed, as discussed above. However, in those populations where I390186 seed forms less than 100% of the population, the identity of the remaining seed is unknown, yet the claims encompass all the individuals of the population. The specification does not describe the non-I390186 seed of the claimed population or essentially homogenous populations, or the hybrids of the populations that are "essentially free" of them. The specification also does not describe any hybrid corn plants produced by crossing I390186 with any other inbred corn plant, except for a hybrid designated "0004411" (page 56-58, Tables 4-5; pages 64-67, Tables 8-9). The descriptions of I390186 and 0004411, however, do not provide any information concerning the description of all other hybrids. The specification does not even identify the other parent of plant 0004411. The description of I390186 is also not indicative of any transgenic plant or I390186 plants comprising single gene conversion(s). The specification indicates that the single locus converted plant only retains "essentially" all of the morphological and physiological characteristics of the starting plant (page 29, lines 16-19). The specification does not describe plants that do not have all of the physiological and morphological characteristics of plant I390186. Further, transgenes may be of any gene, including those that affect more than one trait. The morphological and physiological characteristics of any such plant are not described. A transgene that is a transcription factor, for example, can effect more than just one gene, and multiple traits. Such plants would express different morphological and physiological traits from I390186, which are not described. For claim 27, it is suggested that the types of transgenes contemplated in the specification be listed, provided the prior art teaches those isolated genes. For example, the specification does not describe any gene that confers enhanced yield stability. Given the breadth of the claims

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encompassing populations of I390186 seeds and plants that can comprise other unknown seed and plants, hybrid corn plants expressing any traits and I390186 further comprising any single locus conversion, and lack of guidance of the specification as discussed above, the specification fails to provide an adequate written description of the multitude of corn plants and their parts encompassed by the claims.

4. Claims 1-31 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are broadly drawn towards seed of corn variety I390186; or a population, or an essentially homogeneous population, of seed of corn variety I390186, or a population of I390186 seed essentially free of hybrid seed; an essentially homogeneous population of corn plants produced by growing seed of I390186; a corn plant produced by growing seed I390186, or a part of said plant; a tissue culture of cells from said plant; or said plant further comprising a nuclear or cytoplasmic gene conferring male sterility; any hybrid corn seed produced by crossing corn plant I390186 with any second, distinct inbred corn plant; any hybrid corn plant produced by growing said hybrid seed; inbred corn plant I390186 further comprising any single locus conversion; a method of producing inbred corn plant derived from corn variety I390186 comprising crossing I390186 plants with any second corn plant, and crossing the progeny with itself or any other plant to produce further progeny.

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Since the claimed seed of corn inbred line I390186 is essential to the claimed invention, it must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. If the seed is not so obtainable or available, a deposit thereof may satisfy the requirements of 35 U.S.C. 112. The specification does not disclose a repeatable process to obtain the exact same seed in each occurrence. Since the claimed seed of line I390186 is essential to the claimed invention, it must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. If the seed is not so obtainable or available, a deposit thereof may satisfy the requirements of 35 U.S.C. 112. The specification does not disclose a repeatable process to obtain the exact same seed in each occurrence and it is not apparent if such a seed is readily available to the public.

If the seeds will be deposited under the terms of the Budapest Treaty, then an affidavit or declaration by the applicants, or a statement by an attorney of record over his or her signature and registration number, must also be submitted, stating that the seeds will be irrevocably and without restriction or condition released to the public upon the issuance of a patent. A minimum deposit of 2500 seeds is considered sufficient in the ordinary case to assure availability through the period for which a deposit must be maintained. See 37 CFR 1.801-1.809.

Applicants are also reminded to amend the specification by inserting the ATCC deposit number in pages 5, 10, 22, and 29.

If the deposit will not be made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 CFR 1.801-1.809, Applicants may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number showing that

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(a) during the pendency of the application, access to the invention will be afforded to the Commissioner upon request;

(b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;

(c) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the enforceable life of the patent, whichever is longer;

(d) the viability of the biological material at the time of deposit will be tested (see 37 CFR 1.807); and

(e) the deposit will be replaced if it should ever become inviable.

5. Claims 27, 29, and 30 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are broadly drawn towards seed of corn variety I390186; or a population, or an essentially homogeneous population, of seed of corn variety I390186, or a population of I390186 seed essentially free of hybrid seed; an essentially homogeneous population of corn plants produced by growing seed of I390186; a corn plant produced by growing seed I390186, or a part of said plant; a tissue culture of cells from said plant; or said plant further comprising a nuclear or cytoplasmic gene conferring male sterility; any hybrid corn seed produced by crossing corn plant I390186 with any second, distinct inbred corn plant; any hybrid corn plant produced by growing said hybrid seed; inbred corn plant I390186 further comprising any single locus

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conversion; a method of producing inbred corn plant derived from corn variety I390186 comprising crossing I390186 plants with any second corn plant, and crossing the progeny with itself or any other plant to produce further progeny.

The specification teaches that single locus conversions of the disclosed corn plant refers to plants that are developed through backcrosses wherein essentially all of the desired morphological and physiological characteristics of the inbred are recovered in addition to a single locus transferred by the backcrossing technique (page 29, lines 15-19). However, the specification does not teach any I390186 plants comprising single locus conversions produced by crossing. The specification at pages 34-35 provides an example of a DEKALB proprietary inbred corn plant that was single locus converted. The example summarizes the crosses performed. However, this example leaves out information, such as the number of crosses that were performed at each step. For example, page 35, line 6 recites "backcrossed times 85DGD1". The direction provided in the example is not complete.

It is not clear that single loci may be introgressed into the genetic background of a plant through traditional breeding. Hunsperger et al. (US Patent No. 5,523, 520), Kraft et al. (Theor. Appl. Genet., 2000, Vol. 101, pages 323-326), and Eshed et al. (Genetics, 1996, Vol. 143, pages 1807-1817), for example, teach that it is unpredictable whether the gene or genes responsible for conferring a phenotype in one plant genotypic background may be introgressed into the genetic background of a different plant, to confer a desired phenotype in said different plant.

Hunsperger et al. teach that the introgression of a gene in one genetic background in any plant of the same species, as performed by sexual hybridization, is unpredictable in producing a single gene conversion plant with a desired trait (column 3, lines 26-46). Kraft et al. teach that linkage

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disequilibrium effects and linkage drag prevent the making of plants comprising a single gene conversion, and that such effects are unpredictably genotype specific and loci-dependent in nature (page 323, column 1, lines 7-15). Kraft et al. teach that linkage disequilibrium is created in breeding materials when several lines become fixed for a given set of alleles at a number of different loci, and that very little is known about the plant breeding materials, and therefore it is an unpredictable effect in plant breeding (page 323, column 1, lines 7-15). Eshed et al. teach that in plants, epistatic genetic interactions from the various genetic components comprising contributions from different genomes may affect quantitative traits in a genetically complex and less than additive fashion (page 1815, column 1, line 1 to page 1816, column 1, line 1). In the absence of further guidance, undue experimentation would be required by one skilled in the art to overcome the difficulties and unpredictability of single gene conversions taught in the prior art.

Claim Rejections - 35 USC § 102 & 103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(c) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

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having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 1-31 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Stangland (U.S. Patent No. 6,211,447).

The claims are broadly drawn towards seed of corn variety I390186; or a population, or an essentially homogeneous population, of seed of corn variety I390186, or a population of I390186 seed essentially free of hybrid seed; an essentially homogeneous population of corn plants produced by growing seed of I390186; a corn plant produced by growing seed I390186, or a part of said plant; a tissue culture of cells from said plant; or said plant further comprising a nuclear or cytoplasmic gene conferring male sterility; any hybrid corn seed produced by crossing corn plant I390186 with any second, distinct inbred corn plant; any hybrid corn plant produced by growing said hybrid seed; inbred corn plant I390186 further comprising any single locus conversion; a method of producing inbred corn plant derived from corn variety I390186 comprising crossing I390186 plants with any second corn plant, and crossing the progeny with itself or any other plant to produce further progeny.

Stangland teaches seed of corn plant 22DHQ3, plants produced by growing said seed, and plants and plant parts having all of the physiological and morphological characteristics of corn 22DHQ3 (col. 10, line 62 to col. 13, line 40; claims). It appears that the claimed plants and seeds of the instant invention are the same as 22DHQ3, given that each has buff dry husk color, green fresh husk color, white cob color, and a semi-conical ear shape, for example (Table 3, columns 12-13). Alternatively, if the instantly claimed plants, plant parts, and seeds are not identical to 22DHQ3, then it appears that 22DHQ3 only differs from the claimed plants, plant parts, and seeds due to minor morphological variation, wherein said minor morphological

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variation would be expected to occur in different progeny of the same plant, and wherein said minor morphological variation would not confer a patentable distinction to I390186. Stangland also teaches populations and essentially homogenous populations, of 22DHQ3; production of tissue culture of cells from a plant of line 22DHQ3 and regeneration of plants, wherein the cells are from tissues including flowers, pollen, ovules, protoplasts, among others; a plant produced from tissue culture of 22DHQ3 capable of expressing all of the morphological and physiological characteristics of 22DHQ3; isozyme typing profile of 22DHQ3; methods for producing seed or hybrid seed and plants wherein a plant of inbred line 22DHQ3 is crossed with itself or another corn plant, or another inbred corn plant; or wherein the crossing comprises in pollinating proximity seeds of 22DHQ3 and another inbred corn plant and emasculation of male flowers of the plant that is to be cross-pollinated, and harvested and growing seed to produce a hybrid corn plant; 22DHQ3 further transformed with a single locus conversion, for example a gene conferring male sterility; or wherein the locus is a dominant or recessive allele (col. 17, line 34 to col. 35, line 60; claims). The reference does not teach an SSR profile for 22DHQ3, and the Examiner is unable to determine if the plant taught by the reference possesses the unrecited SSR profile. The Examiner does not have sufficient facts to determine whether this property is inherent to 22DHQ3, and a conclusion of obviousness cannot be determined since it cannot be determined if the SSR profile is different. The Examiner is not in a position to make either a conclusion of "inherency/anticipation" or "obviousness" since the record does not allow one to determine if and how the claimed subject matter differs from the prior art. Accordingly, the burden shifts to Applicant to provide evidence that the prior art would neither anticipate nor render obvious the claimed invention. See In re Best 195 USPQ 430, 433 (CCPA 1977). As

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22DHQ3 is otherwise the same as I390186, the claimed invention was *prima facie* obvious as a whole to one of ordinary skill in the art at the time it was made, if not anticipated by Stangland.

7. Claims 1-31 are rejected.

Contact Information

Any inquiry concerning this communication from the examiner should be directed to Ashwin Mehta, whose telephone number is 703-306-4540. The examiner can normally be reached on Mondays-Thursdays and alternate Fridays from 8:00 A.M to 5:30 P.M. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at 703-306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 and 703-872-9306 for regular communications and 703-872-9307 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.


ASHWIN D. MEHTA, PH.D
PATENT EXAMINER

January 26, 2003